



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D452023; FILE SYMBOL No.: 93809-E; PRODUCT NAME: Axill Solutions Fluazinam 500SC; DECISION No.: 545364; ACTION CODE: R300; FOOD Use: No; COMPANY: Axill Solutions LLC

DATE OUT: May 28, 2019

SUBJECT: End Use Product Chemistry Review
Product Name: Axill Solutions Fluazinam 500SC

FROM: Shyam Mathur, Ph. D
Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO: BeWanda Alexander / Erik Kraft, RM 24, Fungicide-Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Axill Solutions Fluazinam 500SC". The registrant has submitted a CSF for basic formulation and an alternate CSF #1 (both dated October 24, 2018) and the supporting group A & B product chemistry data with MRID Nos. 50700501 and 50700502 respectively. The registrant has also requested waivers for few of the physical-chemical characteristics with MRID No. 50700503. The registrant has claimed that the proposed product is substantially similar / identical to the registered product with Reg. No. 91234-34. CITAB has been asked to determine the acceptability of the proposed basic & alternate CSF's, the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

Product ingredient source information may be entitled to confidential treatment

1. Name of Active Ingredient(s):

Active Ingredient	Reg. No.	NC of AI in product	PC code
			129098

2. Has the registrant claimed substantial similarity to a registered product?

[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.

EPA Reg. No: 91234-34

3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No

4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses. [X] Yes; [] No.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 10-24-2018; Re-submitted - Dated:

☒ Alternate CSF #1 – Dated: 10-24-2018; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Soluble arsenic:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Isomeric ratios:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA
Acid Equivalent:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> NA

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Methanol at > 4%:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA
Sodium nitrate/Sodium nitrite	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50700501
830.1600	Description of materials used to produce the product		X		A	50700501
830.1650	Description of formulation process		X		A	50700501
830.1670	Discussion on the formation of impurities		X		A	50700501
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Proposed standard limits	X		A	Basic CSF dated 10-24-2018
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50700502 Reverse-Phase HPLC-UV (240 nm) for the AI's using external standard calibration. Method validation provided

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Yellowish liquid with mild characteristics odor	A	50700502
830.6315	Flammability	Non-flammable liquid	A	50700502
830.6316	Explodability	Waiver request	A	50700503
830.7000	pH	5.68 (1% dispersion in water) @ 20°C	A	50700502
830.7300	Density (units)	1.251 g/ml (10.43 lbs/gal) at 20°C	A	50700502
830.7100	Viscosity	489.9 mPa.S/60 rpm/40°C 559.9 mPa.S/60 rpm/20°C Non-Newtonian liquid	A	50700502
830.6317	Accelerated Storage stability	TS was found to be stable for two weeks at 54°C when stored in commercial package (fluorinated bottles)	A	50700502
830.6320	Accelerated Corrosion characteristics	After storage at 54 ± 2 °C for 14 days, the packaging material (fluorinated bottles) showed no perforation, darkening, rust and leaking, the test substance is no corrosive to packaging.	A	50700502
830.6314	Oxidation/reduction	This product does not contain an oxidizing or reducing agent; therefore it is requested that the requirement for this data be waived.	A	50700503

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 91234-34) from Product chemistry view point

- ☒ Similar
- ☐ Not similar, give reasons:
- ☐ Identical
- ☐ Not identical
- ☐ Not Applicable

B. Confidential Statement of formula

- 1. Basic CSF (dated: 10-24-2018)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable
- 2. Alternate CSF#1 (dated: 10-24-2018)
 - ☒ Acceptable
 - ☐ Not Acceptable:
 - ☐ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Acceptable with the exception of the guidelines
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

D. Group B Product chemistry data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of the guidelines
- ☐ Not required
- ☐ Data cited
- ☒ Waiver requests: Acceptable ☒; Not Acceptable ☐; Not Applicable ☐
- For the guidelines: 830.6314 (oxidation-Reduction); 830.6316 (explodability)

E. Product Label/Draft Label: Recommendations – Yes ☐; No ☒